

With Love: Using
Promotoras for a
Hispanic Community
Palliative Care
Promotora Palliative
Care

NCT03736031

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Title: Con cariño: Using Promotoras for a Hispanic Community Palliative Care Intervention – A pilot study

Objective/Hypothesis: We hypothesize that the intervention group (promotora-based) will, in comparison to a self-education group (no promotora), show improved quality of life and pain scores and decreased ED visits and ICU admissions. We anticipate that the promotora-based program will be cost-effective.

Specific Aims: (1) To assess the impact of the promotora-based program compared to self-education (usual care) on quality of life scores, pain scores, ED visits, and ICU admissions as assessed via survey completion and the medical record. (2) To perform a cost-effectiveness analysis of this intervention. (3) To utilize our findings to establish a novel, culturally sensitive, outpatient, cancer palliative care program in an underserved, majority Latino, county hospital setting.

Goals of the Research: We anticipate our intervention will increase the rate of palliative care service utilization among underserved Latino cancer patients residing on the US-Mexico border. We believe that by increasing the awareness of palliative care services that there will be a decrease in overall health care costs as well as an overall improvement in quality of life for the Hispanic cancer patients in our community.

Background and Significance: Palliative care is defined as “care given to improve the quality of life of patients who have a serious or life-threatening disease”. The integration of palliative care early in the treatment course of advanced cancer patients has been shown to improve quality of life, increase survival among cancer patients, and decrease overall healthcare costs. (Hay et al., 2017, Temel et al., 2010). Access to end of life care; however, is not equal with significant disparities occurring among minorities and marginalized groups.

A study involving patients with gynecological cancers found that non-white patients were less likely to enroll in hospice or palliative care despite a majority reporting wishing to die pain free and comfortable in their homes (Harris et al., 2009). Latinos are also less likely to have had end of life conversations with health care providers and may therefore be less informed regarding end of life issues such as advance directives. This is despite studies showing that end of life conversations improve advance care planning among Latinos (Shen et al., 2016).

End of life costs are a great burden for many Latinos. Up to 25% or more of healthcare costs are amounted in a patient’s last year of life, making end of life care especially difficult for this group and others of low socioeconomic status (Riley & Lubitz, 2010). In a study by Hanchate et al., it was found that Latinos’ Medicare expenditures are 57% higher than Whites in their last six months of life (\$21,166 vs \$31,702 even with controlling for sex, age, morbidity-burden level, cause and site of death) (Hanchate, Kronman, Young-Xu, Ash, & Emmanuel, 2009). A lack of insurance and immigration status increases this burden. Currently there are 11.1 million undocumented immigrants

in the US which account for 14.6% of the uninsured population. These individuals rarely have access to appropriate end of life care due to costs (Jaramillo & Hui, 2016). Along the US-Mexico border these figures are exponentially increased. In 2008, prior to the Affordable Care Act, nearly half of the US residents living along the Mexico-US border had no health insurance and about 63% of the uninsured were undocumented foreign-born individuals (Su, Pratt, Stimpson, Wong, & Pagán, 2014). The uninsured rate decreased to 31% by 2012 among residents living in the US-Mexico border region; yet the majority remained unable to access health care (Shen, M., Gai, Y., & Feng, 2016).

The lack of insurance, increased cancer-care burden, and cultural barriers are leaving many dying Latinos and their families vulnerable at one of the most difficult times. It is imperative that innovative approaches are considered to provide the best care at the end of life. Moreover, this could potentially decrease costs to Medicare and hospitals.

Our aim is to test the cost effectiveness with respect to the healthcare system with an innovative approach for palliative care education intended to increase the quality of care at the end of life for Latinos in a US-Mexico border town. Our goal is to use promotoras (community health workers) to provide palliative services to patients diagnosed with advanced cancer. This model has demonstrated success in other behavioral modification programs such as those designed to increase cervical cancer screening rates, increase vaccination uptake, and medication adherence. In a program using lay navigators among elderly oncology patients with Medicare it was estimated that a total of 19 million dollars in costs per year was eliminated among the navigated patients. ED visits decreased by 6% per quarter in navigated compared to non-navigated patients, ICU admissions were reduced by 10.6%; and lastly, the cost of using a navigator gave a return on investment of 1:10 (Rocque et al., 2017).

We believe that we can use promotoras in the context of a culturally-sensitive palliative education program. We hypothesize that this intervention will decrease healthcare costs through a reduction in ED visits and ICU admissions. Additionally, we hypothesize that promotoras-based education regarding self-care will reduce depression, improve pain control, and improve overall quality of care as perceived by patients and families in a Latino underserved community.

Innovation:

El Paso, a town in the US-Mexico border, is home to over 800,000 residents of which 82% are Hispanic/Latino, almost a quarter of its population does not have health insurance and 20% lives below the federal poverty line. El Paso along with many other border towns suffers from an increasing burden due to health disparities and lack of health access. It is estimated that along the Texas-Mexico border there is 1 general practitioner for over 6,000 people and this number broadens for many specialties. Cancer is currently the second leading cause of death in El Paso and the majority of these patients do not receive comprehensive palliative care services. We believed that due to the high burden of cancer and cancer related deaths, it was imperative that

palliative services will be offered to these patients. Due to the many barriers that currently exist to providing health care among Latinos in the US-Mexico border such as physician shortage and lack of insurance, a new innovative way to provide these services had to be implemented.

Promotoras, or lay community health care workers, have been imperative in bridging the gap of health care access and disease prevention along the US-Mexico border. The promotora model has been used successfully for disseminating health information, improving cancer screening, vaccinations, and implementation of many public health projects. We believe that this model can also be applied to providing palliative care services and education. This has not been done before. We believe that this new approach will help to improve access in remote areas where access to health care is limited and simultaneously be cost effective.

Research Design and Methods:

Study Population: Our study population will include men and women with advanced cancer or with a new change in prognosis i.e. metastasis or recurrence of primary cancer and/or their caregivers. Participants must be over the age of 18 years and self-identify as Hispanic or Latino. Each patient must be capable of providing consent to participate on the project. The subjects will be recruited from Texas Tech clinics as well as from University Medical Center where they will be invited to participate.

Sample Size:

Promotora study: A total of 150 patients will be recruited and will be randomly assigned to either the control or intervention groups.

Caregiver study: A total of 150 caregivers will be recruited.

Recruitment plan:

Promotora study:

- Each patient will be recruited via the Texas Tech clinics and the University Medical Center (UMC): palliative care service, the UMC cancer navigation program, and the infusion center. Each patient and their caregivers will be invited and those who desire to participate will be contacted by the research staff personnel. A screening survey will be done to see if they first qualify. Patients already enrolled in inpatient or outpatient hospice will be excluded. Interested and qualifying individuals will be consented by the research staff. At this time, the participant will also complete baseline surveys: Demographics, Patient Health Questionnaire-9 (PHQ-9), and Functional Assessment of Chronic Illness Therapy-Palliative Care (FACIT-Pal). Participants can choose whether to fill out the surveys on their own (self-administer) or have a research staff member read the questions and mark the answer choices on their behalf (structured interview).

- Participants will be randomized into either the intervention (also known as the study group or the promotora) group or the control (also known as self-education or control) group. Each participant will continue to receive the standard of care for his or her oncologic diagnosis as determined by his or her treating oncologist over the course of the study. During the study period, all participants will complete baseline (demographics, PHQ-9, FACIT-Pal), interim (adverse events) and exit (adverse events, PHQ-9, FACIT-Pal) surveys. Information pertaining to hospitalizations and emergency room visits will be obtained from their medical records and public health records. The intervention group will have three face-to-face meetings with the promotora. The control group will receive two phone calls.
- If the patient is in the intervention group, the promotora will call the patient in order to invite them to a meeting. Meetings will be arranged by the promotora and the patients. Participants will be encouraged to bring support persons to the promotora meetings.
 - Meeting 1 topic: What is cancer, Medical Management, What is palliative care, Local resources, Goals and Expectations, Discussion. Total time: 45 min
 - Meeting 2 topic: Taking care of self: physical activity, nutrition, pain management, Family Values, Total: 50 min
 - Meeting 3 topic: Caregiver burnout, patient's wishes, revisit Goals and Expectations. Making hard decisions, planning for the future (Power of Attorney, Advance Directives). Local resources, support groups, the grieving process. Exit interview (Re-administration of FACIT-Pal and PHQ-9 and advanced directives) Total: 45 min

At the beginning of each meeting the patients will be asked about adverse events (hospitalizations and ED visits). This data will be validated against the information stored within the patient's medical record

- If the patient is in the control group, they will receive two phone calls. The first phone call will be to ask about adverse events that have occurred since enrollment into the study. The second call will be to ask about adverse events since the first phone call and to administer the exit interview (Re-administration of FACIT-Pal and PHQ-9).

Caregiver study:

All patients recruited to the study will be asked to identify their caregiver to take the caregiver financial survey. The caregiver may be of any race or gender. If the caregiver is with the participant and if they would like to participate, they will be told the survey is completely confidential, voluntary, and they may refuse to answer any question that will make them feel uncomfortable. If the caregiver is not with the participant, we will give the participant a study flyer with research staff contact information. The study may be administered via phone, in person, or via email, based on the caregivers' preference. If

the caregiver would like to participate, they will assigned a participant identification number which will be randomly assigned by REDCap.

Texas Hospital Inpatient Discharge Public Use Data File (PUDF) analysis: Because both arms of the study technically had an intervention simply participating in the study may have also had an impact. A way to assess this would be to compare the rate of hospital events at the end of life to the rate observed in the study. A retrospective chart review of Texas Hospital Inpatient Discharge Public Use Data File (PUDF) will be conducted in which patients have the principal discharge diagnosis field contained an ICD-9 code for a malignant neoplasm (codes 140* through 208*, where the asterisk represents a wild card operator) and the patient was discharged to either hospice-home or hospice–medical facility.

Incentives:

Promotora study: Each participant will receive \$70 for completion of the entire survey set: Participants in the study group will receive \$25 at randomization, \$10 at the first meeting with the promotora, \$10 for the second meeting with the promotora, and \$25 for the third meeting with the promotora. Participants in the control group will receive \$25 at randomization, \$15 will be mailed after the first phone interview, and \$30 will be mailed to participant after second/final phone interview.

Caregiver study: The caregiver will not receive an incentive.

Challenges:

We anticipate that a potential difficulty will be participant retention. Additionally, as we will be recruiting many patients at the end of life, we recognize that hospitalization and death may prevent study completion. As participants are individuals with advanced stage cancer, death is a likely occurrence in many cases and will not be considered an adverse or unexpected event. We will accommodate timing issues by providing the educational meetings every other week. The participants will also be compensated for their time. Additionally, we will enable in person collection of survey materials at the location of patients who are either hospitalized, become confined at home, or who transfer into inpatient hospice over the course of the study. As the participants will have complex medical issues, we will have the support of a gynecologic-oncologist and a medical oncologist for any emergent medical concerns that may arise until the patient may be seen by his or her treating oncologist. We anticipate that the study will take 1 year to complete accrual, 18 months to complete data acquisition and an additional 4-6 months for data analysis, interpretation and reporting. We strongly believe this project will lay the groundwork for a larger, comprehensive, and culturally sensitive palliative program that may be generalized to other centers to decrease the cancer care burden in the Hispanic community.

Statistical Analysis:

For the caregiver portion of the study, we are conducting a pilot study with a working number of 150 participants.

For the patient portion of the study; a required sample size of 150 eligible patients was estimated based on a preliminary power calculation. It was determined with an alpha of .05 and power of 0.8 that a reduction of Emergency Department visits of 79%, 39 patients per arm would be required, however, as the differences in the FACT-G will be more subtle, we would like to recruit 75 patients per arm.

For the PUDF portion of the study, we will be reviewing 588 records.

The data will be analyzed as an intent-to-treat analysis. Because of the multiplicity of Quality of Life (QoL) outcome measures and potential correlations among the scales, each QoL scale was tested at a significance level of .01 (.05/5) to control for the overall type I error at .05. As the overall measure of QoL was the Functional Assessment of Cancer Therapy scale –General (FACT-G), it will be considered the primary QoL outcome.

We will be performing a standard cost-effectiveness analysis using TreeAge software.

Tentative timeline:

	Program Development	May-September 2017
	IRB/Funding	October-November 2017
	Hiring/Training	April 2018
	Rolling recruitment	May 2018-January 2020
	Program Implementation	May 2018- January 2020
	Interim Data analysis, Final data analysis	November 2019 (Interim), January 2020 (Final)
	Program evaluation	January-February 2020
	Written Paper/Poster presentation	January-March 2019

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